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NEW YORK, NY 10151

EXAMINER

ROYDS, LESLIE A

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1614

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/085,239	Applicant(s) WARD ET AL.	
	Examiner Leslie A. Royds	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-42 and 44-50 is/are rejected.
- 7) ☒ Claim(s) 43, 48, 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 40-51 are presented for examination.

Applicant's Amendment and Declaration of Prof. Hans Korting filed October 19, 2007 have each been received and entered into the present application.

Claims 40-51 are pending and under examination. Claims 48-51 are newly added.

Applicant's arguments, filed October 19, 2007, have been fully considered. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and objections are either reiterated or newly applied. They constitute the complete set of rejections and objections presently being applied to the instant application.

Objection to the Claims

Claim 43 remains objected to for depending upon a rejected base claim, but would otherwise be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Objection to the Claims (New Grounds of Objection)

Claim 48 is objected to for misspelling the word --treating-- as "dreating" in line 1 of the claim.

Claim 51 is objected to for depending upon a rejected base claim, but would otherwise be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 44-47 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, for the reasons of record set forth at pages 6-7 of the previous Office Action dated April 19, 2007, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating that the specification clearly indicates that the compositions of the invention can be applied "to that portion or area of the skin which is affected" or the areas "in which treatment is desired" such that the claimed application to skin would be fully understood by those of skill in the art.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

First, it remains that the claims fail to clearly define whether the skin to which the carbenoxolone is topically administered is actually the area of skin affected by, and, thus, in need of treatment, of a hyperproliferative skin disease. Though it is acknowledged that the claim is directed to a method for treating a hyperproliferative disease of the skin (of which the claims are then limited to the specific disorders of psoriasis, acne vulgaris, actinic keratosis, solar keratosis, squamous carcinoma *in situ*, ichthyoses, hyperkeratosis and disorders of keratinization), the claims (in their broadest reasonable interpretation consistent with MPEP §2111) circumscribe methods for treating the disorder by applying the agent to the affected area of skin in need of treatment, but also provides for circumstances wherein *any* portion of the skin is treated with no clear indication that treatment of the disorder would be affected by applying the claimed active agent to an area of skin other than that which is affected. Accordingly, in the absence of a clear indication *in the claims* as to what area and/or type of skin is actually being treated by the claimed method (i.e., whether the area of skin is, in fact, in need of treatment or not), the claims continue to fail to meet the tenor and express requirements of reasonably clarity and precision as set forth under 35 U.S.C. 112, second paragraph, because the skilled artisan would not have been reasonably apprised of the area and/or type of skin intended to be treated, and, thus, tolerated by the instantly claimed

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method.

Here, even if Applicant were to rely upon the discussion presented in the specification in support of the interpretation that the skin of present claims 44-47 is actually affected and in need of treatment, it is again noted that the claims do not recite such a limitation and, thus, are not limited in such a fashion. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Please see *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant is reminded that it is the claims, not the specification, that must be able to stand alone in defining the invention fully, clearly and precisely. The specification teaches an invention, whereas the claims define the right to exclude. *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 [227 USPQ 577] n.14 (Fed. Cir. 1985).

For these reasons provided *supra*, and those previously made of record at pages 6-7 of the previous Office Action dated April 19, 2007, rejection of claims 44-47 remains proper and is **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

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to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 40-42, 44-46 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burchardt et al. (WO 97/15298; 1997), already of record, for the reasons of record set forth at pages 7-13 of the previous Office Action dated April 19, 2007, of which said reasons are herein incorporated by reference.

Newly amended claims 48-50 are properly included in the rejection because Burchardt et al. teaches the treatment of acute and chronic inflammatory disorders, such as psoriasis (p.6, l.1-11), using a glucocorticosteroid, of which carbenoxolone sodium is specifically named, and an LTD4 receptor antagonist (p.1, l.4-6 and p.2, l.3-7). Burchardt et al. expressly discloses that the combination can be used topically as an ointment or cream for application to the skin (p.6, l.18-20). Applicant is further reminded that present claims 48-50 contain the transitional phrase "comprising", which is open transitional language and does not patentably exclude the presence or administration of additional components, such as the LTD4 receptor antagonist of Burchardt et al., to the presently claimed subject. Please see MPEP §2111.03[R-3] for discussion of the interpretation of claim transitional language.

Response to Applicant's Arguments and Declaration of Hans Korting under 37 C.F.R. 1.132

Applicant traverses the application of Burchardt et al. as prior art against the claimed invention, stating that the basic and novel characteristic of the present invention is the administration of carbenoxolone as an inhibitor of the retinoic acid biosynthetic pathway and the specification supports the use of carbenoxolone as "the active ingredient" as one of the basic and novel characteristics of the invention. Applicant submits that, as a result, the phrase "consisting essentially of" would necessarily exclude a material change to the claimed administration, such as the use of an LTD4 receptor antagonist as described in Burchardt et al. Applicant further submits that the claims as previously presented clearly

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indicated that the claimed method comprised the administration of only a single inhibitor of retinoic acid. Applicant relies upon the specification at pages 100-101 (Table 6 of the Proliferation Assay), which clearly shows "that carbenoxolone was administered in the presence of no other inhibitors (see line 6 of Table 6)." Applicant further relies upon the results shown in Figure 10, which shows that carbenoxolone provided the greatest reduction in proliferation. Applicant additionally references the Declaration of Hans Korting in support of the allegation that the recitation of carbenoxolone sodium and corticotrophin in the list of "customary glucocorticosteroids" at page 2 of Burchardt et al. is clearly in error because such agents are not, in fact, glucocorticosteroids. Applicant further asserts that, because of this fact, one of skill in the art would not have been motivated to employ carbenoxolone sodium as the glucocorticosteroid of the combination disclosed by Burchardt et al. because this agent is not actually a glucocorticosteroid.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

First, Applicant's assertion that the claimed method comprises the administration of only a single inhibitor of retinoic acid is not disputed insofar as it is recognized that Applicant's claims are directed to the administration of "an inhibitor of the retinoic acid biosynthetic pathway". However, though the claims recite the administration of carbenoxolone as said inhibitor of the retinoic acid biosynthetic pathway, it remains that the claimed method does not preclude the presence of additional components and/or steps. This is particularly true for the claims that are directed to a method for treating a skin disorder "comprising" the administration of carbenoxolone (claims 44-50), because such language is clearly open and does not patentably exclude additional method steps or administration of additional components.

Regarding the claims that employ the transitional phrase "consisting essentially of" (claims 40-42), Applicant alleges that the basic and novel characteristic of the instant invention is the administration of an inhibitor of the retinoic acid biosynthetic pathway, wherein the inhibitor is carbenoxolone and is "the" active ingredient to be used. While the concept of administering carbenoxolone for the claimed

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therapeutic purpose may very well be a basic and novel characteristic of the presently claimed invention, this characteristic is not materially changed by the disclosure of Burchardt et al. because the reference to Burchardt et al. explicitly teaches the administration of carbenoxolone sodium for an identical therapeutic purpose (i.e., for the treatment of psoriasis), though it is used in combination with an LTD4 receptor antagonist and, thus, meets this assertedly basic and novel characteristic of the invention.

Moreover, Applicant further alleges that the basic and novel characteristic of the instantly claimed invention is not only just the administration of carbenoxolone as an inhibitor of the retinoic acid biosynthetic pathway for the claimed therapeutic purpose, but that carbenoxolone is the sole active ingredient to be administered for the claimed therapeutic purpose. This, however, is not a point well taken because the instant specification clearly provides for embodiments where a combination therapy may be used and still achieve the intended therapeutic objective of the invention. Please see p.76, l.6-13, which states, "Other therapeutic agents suitable for use herein are any compatible drugs that are effective for the intended purpose, or drugs that are complementary to the formulation...The combined treatment is especially important for treatment of an acute or a severe skin proliferation disease. The formulation utilized in a combination therapy may be administered simultaneously, or sequentially with other treatment, such that a combined effect is achieved." As a result, the "basic and novel characteristics" of the invention appear to lie in the administration of carbenoxolone for the claimed therapeutic objective and *not* the administration of carbenoxolone alone since the specification clearly discloses that the invention can still be effectively practiced with used in combination with "any compatible drugs that are effective for the intended purpose".

Accordingly, for the purposes of examination, the transitional phrase "consisting essentially of" fails to exclude the LTD4 receptor antagonist of Burchardt et al. because the combination therapy disclosed by Burchardt et al. meets Applicant's assertedly basic and novel characteristic of the invention (i.e., the administration of carbenoxolone for the claimed therapeutic objective) and there is nothing of

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record to show that the presence of the LTD4 receptor antagonist of Burchardt et al. would materially change (either positively or negatively) the function of the glucocorticoid compound (i.e., carbenoxolone sodium) in treating the psoriasis as disclosed in the reference.

Applicant is reminded that it is the transitional phrase that follows the preamble language that controls the closed or open nature of the claim as a whole. Accordingly, the fact that Applicant recites “consisting essentially of” or “comprising” following the preamble objective of treating a hyperproliferative disease of the skin subject to treatment by inhibition of the retinoic acid biosynthesis pathway, wherein said disease is psoriasis, acne vulgaris, etc., is clearly and obviously indicative of the fact that the claim, *as a whole*, is still open to the inclusion of additional elements, such as the LTD4 receptor antagonist of Burchardt et al. The fact that the claim(s) state “wherein the inhibitor is carbenoxolone” does not limit the elements or steps of the claimed method solely to the administration of carbenoxolone. The placement of the transitional language and the presence of the word “is” only requires that, in order to meet the claim limitations, that carbenoxolone is administered to a subject suffering from any one or more of the claimed diseases. This claimed requirement is clearly and unequivocally met by the teachings of Burchardt et al.

Applicant’s reliance upon Table 6 and Figure 10 in support of the allegation that the specification clearly *intends* for carbenoxolone to be administered as a single agent is again, as before, not persuasive because the claims fail to reflect this intent to solely administer a single agent (i.e., carbenoxolone). The claims recite open transitional language and/or do not preclude the administration of additional active agents. Moreover, Applicant is reminded that, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In other words, and as stated at MPEP §2111.01(II), “Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read

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into a claim when the claim language is broader than the embodiment.” *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004).” Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Accordingly, Applicant’s reliance upon an embodiment presented in the specification as being clearly representative of the *intent* to administer a single agent (i.e., carbenoxolone) is unpersuasive in establishing that the instant claims exclude the combination therapy of Burchardt et al. because the claims are clearly not limited in such a manner. Applicant is reminded that, even though the specification discloses an embodiment wherein carbenoxolone is administered as the sole agent, it is the claims that must be able to stand alone in defining the invention fully, clearly and precisely. Accordingly, if Applicant desires to preclude the administration of any additional agent, especially the LTD4 receptor antagonist of Burchardt et al., then the claims must be amended in such a manner as to clearly close the claim(s) to the administration of a single, sole active agent (carbenoxolone).

Applicant additionally presents the Declaration of Prof. Hans Korting under 37 C.F.R. 1.132 in support of the position that Burchardt et al., in fact, fails to contain a teaching or motivation to use carbenoxolone in the disclosed combination because carbenoxolone is not actually a glucocorticoid (see p.2 of the Declaration filed October 19, 2007) according to Prof. Korting. The Declaration further submits that glucocorticosteroids have a core structure of four fused rings (three 6-membered rings and one 5-membered saturated ring) and have 21 carbon atoms and contrasts the structure of cortisol (“the most important GCS”; see p.2 of the Declaration) with carbenoxolone, which has a core of five fused rings that are all 6-membered and has 34 carbon atoms. In view of this structural difference, Prof. Korting alleges that carbenoxolone is not a glucocorticosteroid and, therefore, the inclusion of carbenoxolone in the list of glucocorticosteroids provided in Burchardt et al. is in error. Applicant further asserts that, in view of this fact, one of skill in the art would not have been motivated to use

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carbenoxolone in the invention of Burchardt et al. because the disclosed combination therapy is an LTD4 receptor antagonist with a glucocorticosteroid and carbenoxolone, though listed as a glucocorticosteroid, is not a glucocorticosteroid.

The Declaration of Prof. Hans Korting under 37 C.F.R. 1.132 has been fully and carefully considered in its entirety, but fails to be persuasive in establishing non-obviousness of the present claims over the prior art of Burchardt et al. The discussion presented in the Declaration of Prof. Korting supporting the assertion that carbenoxolone is not a glucocorticosteroid is based solely upon the fact that carbenoxolone contains a different core structure from that of cortisol, which Dr. Korting asserts is "the most important GCS" (p.2). Though the difference in chemical structures between, for example, cortisol, and carbenoxolone is noted, Dr. Korting fails to provide any disclosure, aside from his own assertions, that glucocorticosteroids must be of the same chemical structure (or at least core chemical structure) as cortisol in order to be considered a glucocorticosteroid. In fact, the state of the art clearly does not support this fact. Please see Stedman's Medical Dictionary, which is cited in response to Applicant's remarks and Declaration (and is not newly cited to form the basis of the instant rejection), which defines a glucocorticoid (i.e., synonymous with glucocorticosteroid) as "any steroid-like compound capable of significantly influencing intermediary metabolism, such as promotion of hepatic glycogen deposition, and of exerting a clinically useful anti-inflammatory effect. Cortisol is the most potent of the naturally occurring glucocorticoids; most semisynthetic glucocorticoids are cortisol derivatives; used as an adjective to designate this type of biological activity" (p.527).

In view of this plain meaning definition of "glucocorticoid", it is clear that the term glucocorticosteroid is not, in fact, limited to a particular chemical structure as alleged by Prof. Korting and Applicant, but rather describes the ability of a compound to function as a promoter of hepatic glycogen deposition and an anti-inflammatory agent. The only structural "limitation", if it could be so named, is that the compound must be "steroid-like", which, in and of itself, does not place any *specific*

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limitations on the actual structural arrangement of the molecule (as long as it bears some resemblance to a steroid compound and functions in the manner as described). In view of these facts, the allegation that carbenoxolone is not a glucocorticosteroid solely on the basis of structural differences between carbenoxolone and cortisol is not persuasive.

Furthermore, the allegation the carbenoxolone is not a glucocorticosteroid is disputed in view of the fact that the art recognized carbenoxolone as an anti-inflammatory glucocorticosteroid. Please see the cited publication to Ghosh et al. ("Mechanism of Inhibition of $3\alpha,20\beta$ -hydroxysteroid dehydrogenase by a Licorice-Derived Steroidal Inhibitor", *Structure*, 1994; 2(10):973-980), which is cited in response to Applicant's remarks and Declaration (and is not newly cited to form the basis of the instant rejection), at the abstract; col.2, para.2, p.973; *et seq.*

In light of this information, it is clear that the teaching contained within Burchardt et al. stating carbenoxolone as a possible glucocorticosteroid for use in the disclosed combination therapy (i.e., LTD4 receptor antagonist with glucocorticosteroid for treating inflammatory disorders, such as psoriasis) is not in error as alleged by Applicant and Prof. Korting. As a result, contrary to Applicant's and Prof. Korting's assertions, the cited reference to Burchardt et al. contains a clear disclosure of and, thus, teaching and motivation to use, carbenoxolone as a preferred glucocorticosteroid to be used in combination with an LTD4 receptor antagonist for treating the disclosed inflammatory disorders (of which psoriasis is specifically named).

In view of the foregoing, the totality of rebuttal evidence of nonobviousness fails to outweigh the evidence in support of the instant conclusion of *prima facie* obviousness when all of the evidence and remarks are considered. Accordingly the rejection is properly maintained.

For these reasons, and those previously made of record at pages 7-13 of the previous Office Action dated April 19, 2007, rejection of claims 40-42, 44-46 and 48-50 is proper and is **maintained**.

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Conclusion

Rejection of claims 40-42 and 44-50 is proper and is **maintained**.

Claims 43 and 51 are objected to for each depending upon a rejected base claim.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

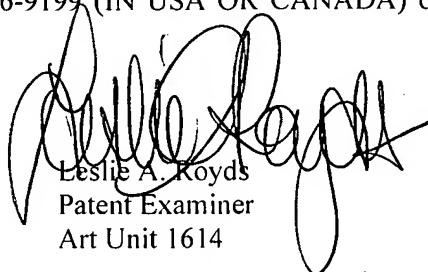
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

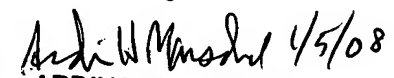
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Leslie A. Royds
Patent Examiner
Art Unit 1614

January 2, 2008



ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER